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OFFICE OF PETITIONS

In re Patent No. 7,521,052
Issued: April 21, 2009
Application No. 10/554,407
Filed: October 24, 2005
Attorney Docket No. 053466-0409

: DECISION ON APPLICATION
: FOR PATENT TERM ADJUSTMENT

This is a decision on the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705" filed April 29, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from zero (0) days to forty-seven (47) days.

The request for reconsideration of patent term adjustment is **DISMISSED**.

On April 21, 2009, the above-identified application matured into US Patent No. 7,521,052 with a patent term adjustment of 0 days. This request for reconsideration of patent term adjustment was timely filed within two months of the issue date of the patent. See 37 CFR 1.705(d).

The Office acknowledges submission of the $200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Patentees request recalculation of the patent term adjustment based on the decision in Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees assert that in view of the decision in Wyeth, they are entitled to a total patent term adjustment of 47 days, the sum of 179 days of patent term adjustment due to exceeding three year pendency and 80 days due to USPTO delay in prosecution minus 212 days of applicant delay.

The 179-day period is calculated based on the application having been filed under 35 U.S.C. 37` on October 28, 2005, and the patent having been issued on April 21, 2009, three years and 179 days later. Patentees assert that in addition to this 179-day period, they are entitled to a period of adjustment due to examination delay pursuant to 37 CFR 1.702(a), of 80 days for the failure by the Office to mail at least one of a

notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a), pursuant to 37 CFR 1.702(a)(1).

Under 37 CFR 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR 1.702 reduced by the period of time equal to the period of time during which patentees failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR 1.704. In other words, it is the period of Office delay reduced by the period of applicant delay. In this instance there is no dispute that there has been no reduction for applicant delay.

Patentees do not dispute that the total period of Office delay is the sum of the period of Three Years Delay (179 days) and the period of Examination Delay (80 days) to the extent that these periods of delay are not overlapping. However, in effect, patentees contend that no portion of the Three Year Delay period overlaps with the period of 14-month examination delay. Accordingly, patentees submit that the total period of adjustment for Office delay is 259 days, which is the sum of the period of Three Year Delay (179 days) and the period of Examination Delay (80 days), reduced by the period of overlap (0 days). As such, patentees assert entitlement to a patent term adjustment of 47 days (179 + 80 reduced by 0 overlap – 212 (applicant delay)).

The Office agrees that as of the issuance of the patent on April 21, 2009, the application was pending three years and 175 days after its filing date.[1]

The Office agrees also that the action detailed above was not taken within the specified time frame, and thus, the entry of a period of adjustment of 80 days is correct. At issue is whether patentees should accrue 175 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as 80 days for Office failure to take a certain action within a specified time frame (or examination delay).

The Office contends that 80 days overlap. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

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[1]Patentees are advised that the instant application was filed under 35 U.S.C. 371.

37 CFR 1.702(b) indicates that a patent is entitled to patent term adjustment if, subject to a number of limitations, the Office fails to issue a patent within three years of the actual filing date of the application (35 U.S.C. 154(b)(1)(B)). In the case of an international application, the phrase "actual filing date of the application in the United States" means the date the national stage commenced under 35 U.S.C. 371(b) or (f). See Changes to Implement Patent Term Adjustment Under Twenty-Year Patent Term, 65 FR 56366, 56382-84, (Sept. 18, 2000), 1239 Off. Gaz. Pat. Office 14, 28-30 (Oct. 3, 2000).

> to the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 35 CFR 1.703(f) provides that:

> To the extent that periods of delay attributable to the grounds specified in § 1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

> If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A),* 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of Patentees. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the

rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding § 1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3-year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

> Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718[2]

As such, the period for over three-year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the commencement date of the application.
In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, October 28, 2005, to the date the patent issued on April 21, 2009. Prior to the issuance of the patent, 80 days of

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[2] The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

patent term adjustment were accorded for the Office failing to respond within a specified time frame during the pendency of the application plus 175 days for failure to issue the patent within three years of the commencement. All of the 175 days for Office delay in issuing the patent overlap with the 80 days of Office delay. During that time, the issuance of the patent was delayed by 175 days, not 175 + 80 days. The Office took 14 months and 80 days to issue a first Office action. Otherwise, the Office took all actions set forth in 37 CFR 1.702(a) within the prescribed time frames. Nonetheless, given the initial 80 days of Office delay and the time allowed within the time frames for processing and examination, as of the date the patent issued, the application was pending three years and 175 days. The Office did not delay 175 days and then an additional 80 days. Accordingly, 175 days of patent term adjustment (not 175 and 80 days) was properly entered since the period of delay of 175 days attributable to the delay in the issuance of the patent overlaps with the adjustment of 80 days attributable to grounds specified in § 1.702(a)(1). Entry of both periods is not warranted. Thus, 175 days is determined to be the actual number of days that the issuance of the patent was delayed, considering the 175 days over three years to the issuance of the patent.

Accordingly, at issuance, the Office properly entered no additional days of patent term adjustment for the Office taking in excess of three years to issue the patent.

In view thereof, no adjustment to the patent term will be made.

Telephone inquiries specific to this decision should be directed to Senior Petitions Attorney Patricia Faison-Ball at (571) 272-3212.

Kery A. Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of Deputy Commissioner
for Examination Policy

1 for DAC

Atty. Dkt. No. 053466-0409

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Osamu OKUDA et al.
Title:	METHODS FOR TREATING INTERLEUKIN-6 RELATED DISEASES
Appl. No.:	10/554,407
International Filing Date:	4/28/2004
371(c) Date:	10/24/05
Patent No.:	7,521,052
Grant Date:	4/21/2009
Examiner:	Prema Maria MERTZ
Art Unit:	1646
Conf. No.:	4578

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. §1.705

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants respectfully request reconsideration of the Patent Term Adjustment (PTA) determined for the captioned patent, which issued on 4/21/2009 as U.S. Patent No. 7,521,052.

The Patent Office determined that the patent was entitled to 0 days of PTA. Applicants believe that this PTA determination was made in accordance with the "Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. §154(b)(2)(A)" published at 69 Fed. Reg. 34238 (Jun. 21, 2004). Under that interpretation of the PTA statute, any PTO delay under 35 U.S.C. § 154(b)(1)(A) is deemed to overlap with any 3-

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year maximum pendency delay under 35 U.S.C. § 154(b)(1)(B), and so, as a practical effect, PTA may be awarded under §154(b)(1)(A) or §154(b)(1)(B), but not both.

On September 30, 2008, the United States District Court for the District of Columbia issued a decision finding that the U.S. Patent and Trademark Office's interpretation of the PTA statute is incorrect. *Wyeth v. Dudas*, Civ. Action No. 07-1492 (JR) (Sep. 30, 2008). The court determined that, under the correct interpretation of the PTA statute, periods of "overlap" are limited to "periods of time . . . [that] occur on the same day." *Wyeth*, slip op. at 8. Thus, a PTO delay under §154(b)(1)(A) overlaps with a delay under §154(b)(1)(B) only if the delays "occur on the same day." *Id.*

Applicants have recalculated PTA for the captioned patent under the court's interpretation of the PTA statute, and have determined that the patent is entitled to 47 days PTA, as shown on the attached sheet, which shows the relevant delays under 37 CFR §§1.702(a) and (b), and under 37 CFR §§1.703(a) and (b).

The attached sheet details the circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

(a) Total of non-overlapping PTO delay under §154(b)(1)(A) & (B):	259 days
(b) Total Applicant delay:	212 days
Final PTA Determination:	47 days

Applicants therefore respectfully request that the patent be accorded 47 days PTA.

The patent is not subject to a terminal disclaimer.

Payment of the requisite fee is submitted herewith. Should no proper payment be enclosed herewith, as by the credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

However, because this PTA error is due to a Patent Office error in interpreting and applying the PTA statute, a refund of the fee is respectfully requested.

Respectfully submitted,

Date APR 2 9 2009

By _____

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Patent Term Adjustment Calculation System

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Docket Number: 053466-0409
Application Number: 10/554407
Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Priority Date	04/28/2003	-910		
Edit Delete	International Filing Date	04/28/2004	-544		
Edit Delete	National Stage Entry (All 371(c) Requirements Met)	10/24/2005	0		
	PCT National Stage Commencement Date	10/24/2005	0		
	14 month From Application date	12/24/2006	426		
Edit Delete	Restriction Requirement	03/14/2007	506	80	
	Restriction Requirement + 3 months	06/14/2007	598		
Edit Delete	Restriction Requirement Response Received at PTO	07/16/2007	630		32
Edit Delete	Non-Final Office Action	10/19/2007	725		
	Non-Final Office Action + 3 months	01/19/2008	817		
Edit Delete	Non-Final Office Action Rsp. Rcv'd at PTO	04/18/2008	907		90
Edit Delete	Final Office Action	06/03/2008	953		
	Final Office Action + 3 months	09/03/2008	1,045		
	3 Year Period Starts	10/24/2008	1,096		
Edit Delete	Notice of Appeal Received at PTO	12/02/2008	1,135		90
Edit Delete	Notice of Allowance	12/16/2008	1,149		
Edit Delete	Issue Fee Paid	03/10/2009	1,233		
Edit Delete	Patent Grant Date	04/21/2009	1,275	179	
			Totals:	259	212
			PTA:	47	

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US007521052B2

(12) **United States Patent**
Okuda et al.

(10) **Patent No.: US 7,521,052 B2**
(45) **Date of Patent: Apr. 21, 2009**

(54) **METHODS FOR TREATING INTERLEUKIN-6 RELATED DISEASES**

(75) Inventors: **Osamu Okuda**, Tokyo (JP); **Noriaki Yoshida**, Tokyo (JP); **Ravinder Nath Maini**, Barnes (GB)

(73) Assignee: **Chugai Seiyaku Kabushiki Kaisha**, Tokyo (JP)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/554,407**

(22) PCT Filed: **Apr. 28, 2004**

(86) PCT No.: **PCT/JP2004/006211**

§ 371 (c)(1),
(2), (4) Date: **Oct. 24, 2005**

(87) PCT Pub. No.: **WO2004/096273**

PCT Pub. Date: **Nov. 11, 2004**

(65) **Prior Publication Data**

US 2006/0251653 A1 Nov. 9, 2006

(30) **Foreign Application Priority Data**

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(51) **Int. Cl.**
A61K 39/395 (2006.01)

(52) **U.S. Cl.** **424/144.1**; 424/141.1

(58) **Field of Classification Search** ..... None
See application file for complete search history.

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Primary Examiner—Prema Mertz
(74) *Attorney, Agent, or Firm*—Foley & Lardner LLP

(57) **ABSTRACT**

A pharmaceutical composition for the treatment of interleukin-6 (IL-6) related diseases, comprising an interleukin-6 antagonist (IL-6 antagonist) and immunosuppressants. The IL-6 antagonist is preferably an antibody to an interleukin-6 receptor (IL-6R).

1 Claim, No Drawings